

ANDA 65-000

May 25, 1999

Bigmar, Inc.
Attention: Peter Stoelzle
9711 Sportsman Club Road
Johnstown, OH 43031-9141

Dear Sir:

This is in reference to your abbreviated new drug application dated December 12, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Daunorubicin Hydrochloride for Injection USP, 20 mg (base)/vial. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

Reference is also made to your amendments dated November 17, and December 22, 1998; February 18, March 19, April 14, and May 5, 1999.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Daunorubicin Hydrochloride for Injection USP, 20 mg (base)/vial to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Cerubidine® for Injection, 20 mg (base)/vial of Bedford Laboratories).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research